## 110TH CONGRESS 1ST SESSION

## S. RES. 241

Expressing the sense of the Senate that the United States should reaffirm the commitments of the United States to the 2001 Doha Declaration on the TRIPS Agreement and Public Health and to pursuing trade policies that promote access to affordable medicines.

## IN THE SENATE OF THE UNITED STATES

June 20, 2007

Mr. Brown submitted the following resolution; which was referred to the Committee on Finance

## RESOLUTION

Expressing the sense of the Senate that the United States should reaffirm the commitments of the United States to the 2001 Doha Declaration on the TRIPS Agreement and Public Health and to pursuing trade policies that promote access to affordable medicines.

Whereas the World Trade Organization (WTO) administers and enforces the Agreement on Trade-Related Aspects of Intellectual Property Rights (in this preamble referred to as "the TRIPS Agreement") to safeguard access to essential drugs;

Whereas, in 1999, the World Health Assembly, by consensus including the United States, adopted Resolution 52.19 on the World Health Organization's Revised Drug Strategy, which expressed concern "about the situation in which

one third of the world's population has no guaranteed access to essential drugs, [and] in which new world trade agreements may have a negative impact on local manufacturing capacity and the access to and prices of pharmaceuticals in developing countries," and urged member states to "ensure that public health rather than commercial interests have primacy in pharmaceutical and health policies and to review their options under" the TRIPS Agreement;

- Whereas, in 2001, the member states of the WTO, by consensus including the United States, adopted the Doha Declaration on the TRIPS Agreement and Public Health, in which member states agreed that "intellectual property protection is important for the development of new medicines", but also expressed "concerns about its effects on prices";
- Whereas the Doha Declaration further states that the TRIPS Agreement "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all";
- Whereas Article 31 of the TRIPS Agreement allows each member state the flexibility to issue compulsory licences which permit the use of the subject matter of a patent, and gives member states broad latitude for such use;
- Whereas the World Health Organization's 2006 Report of the Commission on Intellectual Property Rights, Innovation and Public Health emphasized the need for innovation in medical technologies and access to such innovation, and the report also—
  - (1) states that the Doha Declaration clarifies the right of governments to use compulsory licensing as a

means of resolving tensions that may arise between public health and the protection of intellectual property rights, and to determine the grounds for using compulsory licensing;

- (2) recommends that developing countries provide for the use of compulsory licensing provisions in legislation as one means to facilitate access to affordable medicines through import or local production;
- (3) recommends that bilateral trade agreements not seek to impose obligations to protect intellectual property rights that are greater than those required under the TRIPS Agreement, because such obligations could potentially reduce access to medicines in developing countries; and
- (4) recommends that developing countries should not impose restrictions for the use of, or reliance on, data from pharmaceutical development tests in ways that would exclude fair competition or impede the use of flexibilities built into the TRIPS Agreement, unless such a restriction is required for public health reasons;
- Whereas the Governments of Thailand and Brazil have issued compulsory licenses to gain access to less expensive versions of second-generation anti-retroviral drugs in order to treat a much larger number of HIV/AIDS patients;
- Whereas the Government of the United States has recognized the right of the Government of Thailand to issue compulsory licenses in accordance with the laws of Thailand and the obligations of the Government of Thailand as a member of the WTO;
- Whereas the 2007 "Special 301" Report, the annual review of intellectual property rights protection and enforcement

conducted by the Office of the United States Trade Representative, elevated Thailand to the Priority Watch List, pursuant to section 182 of the Trade Act of 1974 (19 U.S.C. 2242), for reasons including "indications of a weakening of respect for patents, as the Thai Government announced decisions to issue compulsory licenses for several patented pharmaceutical products";

- Whereas the 2007 "Special 301" Report singled out Brazil for having "at times indicated consideration of the use of compulsory licensing on patented pharmaceutical products";
- Whereas the 2007 "Special 301" Report cited 21 developing countries for "inadequate" intellectual property rights protections on pharmaceutical test data;
- Whereas the United States Trade Representative has negotiated or is seeking to complete several bilateral or regional trade agreements with developing countries that contain further obligations to protect intellectual property rights, including—
  - (1) limitations on the grounds for issuing compulsory licenses;
  - (2) requirements that countries adopt periods of data exclusivity on the scientific evidence used to determine that drugs are safe and effective, which either delays the timely entry of generic drugs into the market or forces competitors producing generic drugs to invest in costly, time-consuming, and redundant clinical trials, including trials that violate ethical rules concerning the repetition of experiments on humans;
    - (3) extensions of patent terms beyond 20 years;
  - (4) linkage between drug registration and assertions of patent protection, so that agencies responsible for the

regulation of drugs are prohibited from granting marketing approval to a generic version of a medicine if the product is covered by a patent; and

(5) obligations to extend patent protection to minor improvements in, or new uses of, older products; and

Whereas the United States is a user of flexibilities provided in the TRIPS Agreement, including the use of involuntary authorizations to use the subject matter of patents in a number of important sectors, including medical devices, software, and automobile manufacturing: Now, therefore, be it

- 1 Resolved, That it is the sense of the Senate that the
- 2 United States should—
- 3 (1) honor the commitments the United States
- 4 made in the 2001 World Trade Organization Doha
- 5 Declaration on the TRIPS Agreement and Public
- 6 Health, which allows member states of the World
- 7 Trade Organization to use "to the full" the flexibili-
- 8 ties in the Agreement on Trade-Related Aspect of
- 9 Intellectual Property Rights (in this resolution re-
- ferred to as "the TRIPS Agreement") "to protect
- public health and, in particular, to promote access to
- medicines for all," including the issuance of compul-
- sory licenses on grounds determined by member
- states;
- 15 (2) not place countries on the "Special 301"
- Priority Watch List under section 182 of the Trade
- 17 Act of 1974 (19 U.S.C. 2242) for exercising the

- flexibilities on public health provided for in the TRIPS Agreement, such as issuing compulsory licenses to obtain access to generic medicines in accordance with the Doha Declaration;
  - (3) not ask trading partners who are developing nations to adopt measures to protect intellectual property rights that relate to public health in excess of protections required in the TRIPS Agreement; and
  - (4) support new global norms for promoting medical research and development that seek to provide a sustainable basis for a needs-driven essential health agenda.

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